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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,606	03/11/2004	Masato Kurokawa	042190	3867

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EXAMINER	
GUDIBANDE, SATYANARAYAN R	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
07/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/797,606	KUROKAWA ET AL.	
	Examiner	Art Unit	
	Satyanarayana R. Gudibande	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10* is/are pending in the application.

4a) Of the above claim(s) *8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☒ Claim(s) *10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Arg-Gly-Asp and auxiliary amino acid sequence of Gly-Ala-Gly-Ala-Gly-Ser and polyalkylenepolyamine in their response to election restriction filed on 10/7/05 was acknowledged on 1/29/05 in a non-final office action.

Applicant's amendment to claims in the response flied on 4/17/07 has been acknowledged.

Claims 1-8 and 10 are pending.

Claims 8 have been withdrawn from further consideration as being drawn to non-elected invention.

Claim 9 has been canceled.

A new claim, Claim 10 has been added.

Claims 1-7 and 10 are examined on the merit.

Any objections and rejections not specifically mentioned here is considered withdrawn.

Claim Objections

Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Maintained Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 6,184,348 B1 issued to Ferrari, et al., in view of US 5,916,585 issued to Cook, et al., as stated in our office action dated 10/20/06 for claims 1-7 and 9.

Applicants argue that Ferrari relates to a recombinantly produced proteinaceous polymer composition and the cited reference does not teach that a polypeptide and a sheet are bonded by a chemical bond. Applicants argue that Cook reference relates to a biodegradable material for immobilization of bioactive species. Applicants point out that the cross-linking agent that cross-links hydrophilic polymer surfactant polyethyleneimine does not cross-link with the hydrophobic support member. Applicants cite the example 18 of the Cook reference and argue that the EGS

reagent used as the cross linking agent is a reagent that reacts with amino groups and does not react with the PGA:PLA fiber mesh used as the hydrophobic mesh. Applicants further argue that Cook describes a biodegradable material useful for an implantable construction with immobilized bioactive species and for biodegradable Cook describes poly(glycolic acid) as the preferred species for hydrophobic support and polyurethane is not preferably used. Applicants also state that Cook reference does not disclose that the acceleration of epidermal regeneration and rapid cure of wounds can be obtained by using the wound dressing of the present invention having above characteristics.

Applicant's arguments filed 4/17/7 have been fully considered but they are not persuasive. Because, applicants statement that the primary reference of Ferrari discloses a recombinantly produced proteinaceous polymer and does not disclose that a polypeptide and a sheet are bonded by a chemical bond is not persuasive. The fact that the protein polymer derived from recombinant methods or made by chemical synthesis should have no bearing on the performance of the protein or peptide polymer. The fact the protein polymer is coated on wound dressing illustrates that there is a kind of chemical bonding such as hydrophobic, hydrogen bonding or ionic interaction present between the layers. The specification of the instant application provides a definition of chemical bonding as '**an ionic, hydrogen bonding, a covalent bonding and/or the like and/or physical adsorption (adsorption by van der waals force)**' (page 17, lines 2-6). Therefore, a physical adsorption is sufficient to meet the limitations of the claim 1 of the instant application.

With regard to arguments that Cook, et al., reference relates to a biodegradable material for immobilization of bioactive species, applicants are arguing a limitation that is not recited in the instant application. Applicants argument that cross-linking agent that cross-links hydrophilic polymer surfactant polyethyleneimine does not cross-link with the hydrophobic support member and applicant's reference to example 18 of the Cook reference that the EGS reagent used as the cross linking agent is a reagent that reacts with amino groups and does not react with the PGA:PLA fiber mesh used as the hydrophobic mesh is not valid, because, the process of coating of the gentamycin on to the cross linked PEI involve steps wherein the gentamycin is adsorbed on the surface reversibly indicating that the bioactive molecule is in a dynamic relationship with respect to the membrane on which it is coated and hence the bioactive molecule is attached to the polymeric matrix via chemical bonding which could be hydrophobic, hydrogen bonding, ionic or physical adsorption interaction. It is clear from example 14 of the cited reference (column 21, lines 19-33), that the method of attaching cell adhesion peptide involves sequential addition of reagents to the fiber mesh in solution phase. The mesh is treated with a cross-linking reagent for 10 minutes followed by rinse step, and the rinse step was followed by placing the mesh in a solution of adhesion peptides, which reacts with the polymer of the first layer. This is a clear indication that the cell adhesion peptide is chemically boded to the polymer of the first layer.

Applicant's argument that the preferred polymer in Cook's reference is a biodegradable polymer poly(glycolic acid) and not polyurethane as required by claim of the instant application is not persuasive because, Cook also discloses the hydrophobic polyurethane as a support polymer base (column 10, line 6). However, poly(glycolic acid) may be a preferred embodiment, but that does not preclude the teaching of polyurethane polymer in the cited reference.

Applicants argument that Cook does not disclose that the acceleration of epidermal regeneration of rapid cure of wounds is not persuasive, because, the reference teaches that the implantable polymeric material is used as structural supports for guiding tissue regeneration, as sutures, staples, meshes and as protective barrier during wound healing (column 1, lines 18-22).

Thus the rejection as stated in our previous office action dated 10/20/06 under the obviousness statute is proper and hence is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Satyanarayana R. Gudibande, Ph.D.
Art Unit 1654

7/9/08
ANISH GUPTA
PRIMARY EXAMINER